TUKOL MAX ACTION COLD, SORE THROAT AND COUGH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid
Genomma Lab USA, Inc

Tukol Max Action Cold, Sore Throat & Cough - 516

Drug Facts

Active ingredients
(in each 20 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCL 10 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- cough
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses (20 mL each) in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: skin reddening, blisters and rash.

If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, persists more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatic, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping an MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma chronic, bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if

You are taking the blood thinning drug warfarin

When using this product

When using this product do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough comes back or occurs with fever, rash or persistant headache
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur. These could be signs of a serious condition.

If pregnant or breast-feeding

as a health professional before use

Keep out of reach of children

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed**
- Do not take more than 4 doses in any 24 hours
- This adult strength product is not intended for use in children under 12 years of age
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- dose as follows

age	dose
adults and children 12 years of age and older	20 mL every 4 hours
children under 12 years of age	do not use

Other information

- Each 20 mL contains: **sodium 10 mg**
- store between15-30°C (59-86 °F), do not refrigerate

Inactive Ingredients

Anhydrous citric acid, edetate disodium, FD&C Blue # 1, FD&C Red # 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

1-877-994-3666
Monday to Friday from 8 am to 6 pm, Central time

Tukol MAX ACTION Cold, Flu and Sore Throat

Tukol® MAX ACTION

DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

ACETAMINOPHEN/Dextromethorphan HBr/Guaifenesin/Phenylephrine HCl

Relieves

- Minor aches and Pain
- Fever
- Nasal & Chest Congestion
- Cough

Ages 12+
6 FL OZ (177 mL)

Distributed by:
Genomma Lab USA, Inc.
Houston, TX 77098

TUKOL MAX ACTION COLD, SORE THROAT AND COUGH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50066-516
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-516-25	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/16/2016	

Labeler - Genomma Lab USA, Inc (832323534)

Registrant - Genomma Lab USA, Inc (832323534)

Revised: 1/2024

Genomma Lab USA, Inc